

# Industry Coalition on 21 CFR Part 11

Advanced Medical Technology Association  
America's Blood Centers  
Animal Health Institute  
Biotechnology Industry Organization  
Consumer Healthcare Products Association  
Cosmetic, Toiletry, and Fragrance Association  
Council for Responsible Nutrition  
Council on Radionuclides and Radiopharmaceuticals  
Generic Pharmaceutical Association  
Medical Device Manufacturers Association  
National Electrical Manufacturers Association  
National Food Processors Association  
National Grain and Feed Association  
Pharmaceutical Research and Manufacturers of America

April 28, 2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane,  
Room 1061  
Rockville, MD 20852

Re: Docket Nos. 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539  
Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures-  
Scope and Application;" Availability of Draft Guidance and Withdrawal of Draft Part 11  
Guidance Documents and a Compliance Policy Guide

Dear Sir/Madam:

I am submitting the following comments on the above noted draft guidance on behalf of the Industry Coalition on 21 CFR Part 11 (Coalition). The Coalition comprises 14 trade associations representing manufacturers of FDA-regulated products, including foods, drugs, cosmetics, veterinary drugs, and medical devices. The Coalition has had numerous discussions with FDA over the past four years as the Agency moved forward to publish guidance clarifying compliance issues in a number of different areas. This ongoing dialogue between Industry and FDA has been extremely useful not just in increasing the awareness of issues and concerns, but also in resolving very complex existing issues and staying current with emerging issues created as new technology is introduced into manufacturing systems and processes.

The Coalition is pleased that FDA has issued a new draft guidance that takes a risk-based approach to compliance. The Coalition strongly supports this risk-based approach as a more realistic and effective way to protect public health, but because Part 11 affects all the FDA centers and the Office of Regulatory Affairs there remains much to be done. Integrating risk based processes into Part 11 computer system validation, audit trails, and electronic data retention will take time and this reality should be clearly recognized in FDA's plans for future guidance, enforcement and internal training.

The Coalition continues to believe that an ongoing dialogue on the critical issues is the best way for all parties to ensure effective compliance. FDA as well as industry has a vested interest in developing sound approaches to manage and maintain electronic records. The Agency will be receiving more industry regulatory submissions in electronic form as both parties move towards paperless environments. This means that

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Industry Coalition Comments on New Scope of Part 11  
April 28, 2003  
Page Two

FDA will confront the same issues as industry is facing with respect to validation of systems and processes, electronic signatures, and the long term maintenance of electronic documents. Practical solutions must be sought for all of these matters. As the FDA moves forward in finalizing this approach, it should clarify that the risk-based approach applies to all activities subject to Part 11 and not just those highlighted in this guidance document.

A risk-based approach will also acknowledge that some records have decreasing value over time. This will assist both the FDA and regulated industry in determining what records need to be archived, in what form and for how long. As the Coalition has noted to FDA in the past, long term record maintenance is one of the most vexing problems we face.

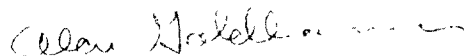
In two major areas, FDA has made good initial efforts to address critical areas. The guidance on computer validation that was developed by the Center for Devices and Radiological Health is a sound document that covers the major issues on this topic (*General Principles of Software Validation; Final Guidance for Industry and FDA Staff* (FDA, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, 2002). In addition, the Coalition supports the use of System Time rather than Local Time in time stamps as a good practice and recommends that this practice be incorporated into a future guidance.

The Coalition is pleased to see that FDA has withdrawn the Compliance Policy Guide and will be exercising discretion prior to taking regulatory action. The Coalition believes that this is a critical issue, and FDA must make an effort to work with the field inspectors to explain how this will be conceptually applied in practice.

The FDA's Guidance for Industry: Computer Systems Used in Clinical Trials is very much oriented toward Part 11, but was not withdrawn. In cases where there is a conflict between this clinical trials guidance and the Part 11 Scope and Application guidance, (e.g., legacy systems, validation, audit trails, and record retention issues), the FDA should clarify that the new Part 11 Scope and Application guidance will take precedence over the older guidance on Computer Systems Used in Clinical Trials.

The Coalition looks forward to the finalization of this draft guidance as a first step towards a reasonable approach to Part 11 Compliance. We look forward to a continuing discussion with FDA on areas of mutual interest.

Sincerely,



Chair, Industry Coalition on Part 11 &  
Associate Vice President for Regulatory  
Affairs; Pharmaceutical Research and  
Manufacturers of America